UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.* DAVID KESTER, *et al.*	)	Case No. 11-CIV-8196 (CM) (JCF)
Plaintiffs,	)	
NOVARTIS PHARMACEUTICALS CORPORATION, *et al.,*	)	
Defendants.	)	

LITIGATING STATES' MEMORANDUM OF LAW IN OPPOSITION TO NOVARTIS' MOTION TO COMPEL FURTHER DISCOVERY RESPONSES

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The plaintiff states of California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington and Wisconsin (the "Litigating States") respectfully submit this Memorandum of Law in Opposition to Novartis Pharmaceuticals Corporation's ("Novartis") Motion to Compel Further Discovery Responses (ECF No. 245).

PRELIMINARY STATEMENT

This case is about how Novartis corrupted the medical judgment of pharmacies by inducing them to recommend Novartis' drugs to patients and doctors. Utilizing a corporate strategy to exploit the influence of certain specialty pharmacies, Novartis paid kickbacks to these pharmacies to get them to act as an undisclosed sales force for Novartis' drugs. In the case of Exjade, Novartis paid kickbacks through rebates and a distribution network that gave it control over which pharmacies could fill prescriptions. After Exjade sales did not meet Novartis' expectations, Novartis conditioned the receipt of valuable prescription referrals to certain specialty pharmacies on their using their influence by recommending Exjade to patients.

In this case, Novartis does not want to focus on its conduct. Rather, its strategy is to claim that the government engages in similar conduct. Nothing in Novartis' moving brief or the 56 exhibits it provided to the Court suggests that this is the case, but even *if* governmental entities had engaged in similar conduct, it would not provide Novartis with a defense. The issue in this case is whether *Novartis* paid kickbacks to a specialty pharmacy in violation of anti-kickback laws and regulations and thereby caused the submission of false claims to the Litigating States' Medicaid programs. In addition, Novartis has not pointed to any dispute about the interpretation of anti-kickback laws and regulations or explained how any such dispute about the law would justify fact discovery about the "contours" of certain government programs. As a

result, the conduct of governments is not relevant, and Novartis' claim that such conduct is "unquestionably" relevant is nothing more than conclusory hyperbole.

Novartis' discovery requests are also incredibly overbroad and burdensome. Novartis is seeking expansive discovery from every agency of the Litigating States, including:

- All documents about the "involvement" of any specialty pharmacy in any government activity (Ex. CC, Req. No. 39)[1];
- Documents relating to the "views" of any state agency about "adherence efforts" and methods used to measure medication adherence (Ex. CC, Req. Nos. 36, 38); and
- All documents about the "administration" of Exjade (Ex. CC, Req. No. 37).

In an effort to compromise, the Litigating States offered to produce documents about Exjade from the state agencies that run the Litigating States' Medicaid programs. Novartis declined this offer and insisted on taking irrelevant, burdensome discovery from every agency of the Litigating States. The Court should reject Novartis' attempts to take this type of discovery.

With respect to the agencies that do not run the Litigating States' Medicaid programs, Novartis has failed to show that these agencies should be aggregated for purposes of discovery. Courts in New York and California have explicitly rejected efforts to obtain party discovery from every state agency, and Novartis has offered no substantive reason to depart from these precedents here. The Litigating States' Medicaid programs were the agencies that paid the false claims that Novartis caused to be submitted, and the Litigating States are producing documents from the agencies that run their Medicaid programs. Moreover, Novartis' overbroad discovery

[1] "Ex." or "Exs." refers to the exhibits attached to the September 10, 2014 Declaration of Manisha M. Sheth (ECF No. 248), which was submitted by Novartis in connection with its Motion to Compel.

request have sought documents from entities whose documents are not within the control of the Attorneys General who brought this case or the agencies that run the Litigating States' Medicaid programs. Novartis' contention that the agencies that administer the Litigating States' Medicaid programs control the documents of entities like state hospitals because they are Medicaid providers has no basis. The Litigating States' Medicaid programs can obtain documents from Medicaid providers for the purposes of conducting audits. They do not have control over such documents in order to fulfill the requests of private litigants in discovery.

BACKGROUND

The Exjade Kickback Scheme

The Litigating States' complaints lay out a straightforward scheme in which Novartis paid kickbacks to specialty pharmacies to boost sales of Novartis' iron-reduction drug, Exjade. (MS FAC ¶¶ 1-2.)[2] Novartis launched Exjade in 2005, but by early 2007, Novartis discovered that its attempts to expand the market for the medication to patients who traditionally had not taken iron-reduction medications was not meeting Novartis' expectations. (*Id.* at ¶¶ 98, 101.) Novartis recognized that one of the main reasons was side effects associated with Exjade that frequently led patients to discontinue taking the drug after fewer than six months. (*Id.* at ¶¶ 296-97.)

To address this problem, Novartis turned to BioScrip, Inc. ("BioScrip"), which was one of three specialty pharmacies hired by Novartis to dispense most Exjade prescriptions around the

[2] "MS FAC" refers to the First Amended Complaint In Intervention of the States of Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, and Wisconsin Against Novartis Pharmaceuticals Corporation. (ECF No. 257.) The states of California and Washington filed their own complaints that make the same substantive allegations against Novartis. (ECF Nos. 162, 82.) For efficiency, this Memorandum will cite to the multistate First Amended Complaint referenced above.

country by mail. (*Id.* at ¶¶ 1, 3, 103-105.) Novartis was able to distribute Exjade through the three pharmacies by encouraging doctors to submit prescriptions to a "hub" that Novartis controlled. This hub, in turn, gave the prescriptions nearly exclusively to the three specialty pharmacies. (*Id.* at ¶¶ 89, 92.) In early 2007, Novartis leveraged its control of Exjade prescriptions by threatening to reduce or eliminate prescription referrals to BioScrip if the pharmacy did not undertake efforts to keep patients on Exjade longer. (*Id.* at ¶¶ 101-107.) In response, BioScrip agreed to provide one-sided information to patients about the benefits and risks (*i.e.* side effects) of taking Exjade as a matter of course. (*Id.* at ¶¶ 106-108.) In addition to recommending that patients refill their prescriptions, BioScrip agreed to call patients who had stopped taking Exjade and encourage them to restart the drug. (*Id.* at ¶ 106.)

Thereafter, to continue to induce BioScrip to recommend Exjade to patients, Novartis set up a contest between the three pharmacies in which it gave more prescription referrals to the specialty pharmacy that kept patients on Exjade the longest. (*Id.* at ¶ 118.) In addition, Novartis paid increased rebates and discounts to BioScrip that were designed to incentivize BioScrip to continue to recommend Exjade and "maximize[] length on therapy." (*Id.* at ¶¶ 113-126.)

In sum, Novartis paid kickbacks to BioScrip in the form of prescription referrals and rebates to induce BioScrip to "recommend" Exjade to patients in violation of the federal Anti-Kickback Statute ("AKS") and state laws and regulations prohibiting kickbacks. Under the federal AKS, it is illegal to "offer[] or pay[] any remuneration" (*i.e.* anything of value) "to induce" someone to "recommend" a product that is paid for by a federally-funded health care program. 42 U.S.C. § 1320a-7b(b)(2)(B). Medicaid is one such program because it is funded by both state and federal monies. (*Id.* at ¶¶ 35-37.)

Each of the Litigating States runs a Medicaid program that paid claims it received from BioScrip for Exjade prescriptions during the period in which BioScrip received kickbacks from Novartis. (*Id.* at ¶¶ 37, 63, 65-66.) As a result, Novartis caused the submission of false claims to the Litigating States' Medicaid programs for which Novartis is liable under each state's False Claims Act or similar statutes. The Litigating States' complaints allege that the claims submitted by BioScrip were false by virtue of express or implied certifications by BioScrip that BioScrip submitted the claims in compliance with the AKS or similar laws and regulations. *See U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196 CM, 2014 WL 4401275, at *7 (S.D.N.Y. Sept. 4, 2014) (Novartis V), citing *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196 CM, 2014 WL 4230386, at *13-14 (S.D.N.Y. Aug. 7, 2014) (Novartis IV).

Novartis' Discovery Requests

Novartis' first set of document requests contained 46 requests that sought a wide range of documents concerning the Litigating States' pre-suit investigation, support for the allegations in the Litigating States' complaints, and data on the thousands of Medicaid patients who received Exjade, among other things. (Ex. CC.)[3] In its motion, Novartis seeks to compel production in connection with seven of Novartis' requests. Mov. Br. at 10, 20-21 (*citing* Ex. K, Req. Nos. 36, 38-39, 37, 44, 46, and 42.)[4]

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[3] Novartis sent separate requests to each of the 11 Litigating States. These requests were substantively the same, though they were different insofar as they sometimes referred to specific state agencies. Ten of the 11 Litigating States provided Novartis with one consolidated response, which was based on the requests directed to the state of Washington. (Ex. CC.) California provided a separate response (Ex. BB) and also responded separately to a second set of document requests from Novartis that were directed only to California (Ex. DD).

[4] "Mov. Br." refers to Novartis Pharmaceuticals Corporation's Memorandum of Law In Support

Adherence Requests (Ex. CC, Req. Nos. 36, 38, 39): The first group of requests concerns the "views" of the Litigating States about "medication adherence" programs and specialty pharmacies as well as all documents relating to any "medication adherence" programs developed by the Litigating States that involve specialty pharmacies. These requests are directed at every department of each of the Litigating States, though the requests specifically mention state-run hospitals, state pharmacy boards, and the entities that run the Litigating States' Medicaid programs.

More specifically, Request No. 37 seeks "the views" of each Litigating State "relating to the effectiveness or utility of different types of adherence efforts" and four other topics, including the patient groups "that should or should not be included in any calculation … of adherence." Request No. 38 seeks all documents created by any agency of the Litigating States about the cost-effectiveness of adherence programs, and Request No. 39 seeks all documents from all state agencies about the "involvement" of specialty pharmacies in any "activities, programs, plans or initiatives" relating to adherence or any state run health care program.

The Litigating States objected to these requests as irrelevant, overbroad, and unduly burdensome, among other things. In addition, the Litigating States objected to the requests to the extent they did not have custody, possession, or control of documents beyond the agency that runs each states' Medicaid program, which are known under federal law as the Single State Agency ("SSA"). *See* 42 C.F.R. § 431.10.

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of Its Motion to Compel Further Discovery Responses (ECF No. 246). Novartis' motion also refers to two requests directed solely at California that are duplicative of Novartis' prior requests. (*See* Ex. V, Req. Nos. 50 and 51, which explicitly refer to prior request Nos. 36-36 in Ex. K.)

Despite their objections to the relevance, breadth, and burden of Novartis' requests, in an effort to compromise, the Litigating States agreed to search for documents responsive to these requests that relate to Exjade at their respective SSAs.

Exjade Requests (Ex. CC, Req. Nos. 37, 44, 46): The second section of Novartis' moving brief is devoted largely to documents relating to "immunosuppressive therapies for kidney transplant patients." Mov. Br. at 16-19. These requests relate to another Novartis drug, Myfortic, which is given to transplant patients to help prevent organ rejection. However, Novartis has not issued any Myfortic requests to the Litigating States and therefore this portion of Novartis' motion does not pertain to the states. (Exs. CC, DD.)

With respect to Exjade, Novartis sought all documents "relating to the administration of or adherence to Exjade" from all state entities, including every state hospital or pharmacy board. (Ex. CC, Req. No. 37.) In addition, Novartis' requests seek all treatment protocols or documents provided to Exjade patients at all state hospitals. (Ex. CC, Req. Nos. 44-45.)

As with Novartis' other requests, the Litigating States objected to these requests as to breadth and undue burden as well as on the ground that Novartis' requests sought documents from non-SSA entities that were not in the Litigating States' possession, custody, or control. Accordingly, the Litigating States have agreed to produce documents concerning Exjade from their SSAs that run their Medicaid programs but not from other state entities.

Settlement Communications with BioScrip (Ex. CC, Req. No. 42): Novartis' document requests also sought communications between counsel for the government plaintiffs and BioScrip regarding certain stipulations of fact in which BioScrip admitted several aspects of the scheme described in the Litigating States' complaints. (Ex. CC, Req. No. 42.) The parties

reached an agreement concerning the scope of such production, and the United States, New York, and Washington have completed their productions on this subject. None of the other Litigating States have located documents on this topic. Accordingly, this portion of Novartis' motion is moot, as Novartis has acknowledged in a letter to the Court. (ECF No. 269.)

Novartis' Freedom of Information Requests

Recently, the Litigating States have learned that Novartis has served requests under various freedom of information laws on some of the entities from which it is seeking discovery in this case. Specifically, such requests have been sent to state hospitals as well as the Litigating States' SSAs. Novartis did not inform counsel for the Litigating States about these requests.

ARGUMENT

I. NOVARTIS' ADHERENCE REQUESTS ARE NOT RELEVANT AND ARE NOT LIKELY TO LEAD TO ADMISSIBLE EVIDENCE

The core issue in this case is whether Novartis induced BioScrip to "recommend" Exjade to patients in violation of the AKS and similar anti-kickback laws and regulations. *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 CIV. 8196 CM, 2014 WL 4401275, at *3 (S.D.N.Y. Sept. 4, 2014) (Novartis V). While there are certain statutory exceptions and regulatory "safe harbors" to the AKS, none of them specifically concern whether a defendant was operating a purported "medication adherence" program. *See* 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952. As a result, none of Novartis' adherence requests have any bearing on whether Novartis violated the AKS and caused the submission of false claims.

In its moving brief, Novartis goes to great lengths to avoid discussing the AKS. Instead, it discusses "medication adherence" programs and suggests that government support for "refill reminder programs" gives Novartis a defense in this case. (Mov. Br. at 9.) The *only* legal support that Novartis offers for its position is *U.S. ex rel. Finney v. Nextwave Telecom, Inc.*, 337 B.R. 479, 488 (S.D.N.Y. 2006). In that case, the Court cited another case stating that "unresolved disputes about the proper interpretation of a statute or regulation should not lead to suits under the FCA, at least where a claimant's interpretation of the governing law is reasonable." *Id.* at 488. In this case, however, Novartis has not pointed to any real "unresolved dispute" over the interpretation of the *AKS* in its moving brief (or in its recent motions to dismiss, which were largely denied). As a result, Novartis' claim that the "reasonableness" of its conduct will be a "critical issue" is false. (Mov. Br. at 11.) Moreover, the *Finney* comment

applies to whether there is a legitimate legal dispute about what conduct is prohibited – not whether the government did or did not engage in conduct similar to a defendants.

There is no dispute that Novartis' state of mind is at issue in terms of whether it "knowingly" caused the submission of false claims by BioScrip. MS FAC ¶ 31, *citing* N.Y. False Claims Act, State Fin. Law § 189(1). To prove its state of mind, Novartis must point to things it was aware of in the relevant time period. Documents in state government files, such as views about adherence programs at every state hospital, are not relevant to this inquiry as courts have held in similar circumstances. *See SEC v. Bankatlantic Bancorp, Inc.*, 285 F.R.D. 661, 668 (S.D. Fla. 2012) (documents in SEC's files "cannot provide probative information" about the defendants' intent); *U.S. v. Elsass*, No. 2:10-CV-336, 2011 WL 3900846, at *5 (S.D. Ohio Sept. 6, 2011) ("Even assuming that actions or positions taken by IRS employees are relevant to the defenses of reasonable cause and willfulness, it is only those actions or those positions of which Defendants had actual knowledge that would be relevant.").

Novartis also offers no support for its contention that what governments "deem[] appropriate and desirable in conducting [their] own affairs" justifies its adherence requests. (Mov. Br. at 11.) Putting aside the issue that the government is a payor of health care claims, as opposed to a provider of products paid for by health care programs, government conduct is not a defense to the AKS. There is no such exception to the AKS in the language of the statute, the case law, or in Novartis' brief. As a result, Novartis' contention that government conduct is "unquestionably" relevant is nothing more than an unsupported conclusory statement that cannot justify its expansive discovery requests. (Mov. Br. at 11.) The same can be said for Novartis' claim that it has a defense because its conduct was "consistent with industry standard." (Mov.

Br. at 10 n.5.) Indeed, as Novartis' own compliance policies explicitly recognize, "[t]he fact that a particular arrangement is common in the health care industry is not a defense." (MS FAC ¶ 73.)

In sum, Novartis has failed to show that its adherence requests are relevant to the claims in this case and its motion to compel as to those requests should be denied.[5] *See Freedman v. Weatherford Intern.*, No. 12 Civ. 2121, 2014 WL 3767034, at *3 (S.D.N.Y. July 25, 2014) (*Francis, J.*) (party seeking discovery bears the burden of showing relevance).

II. NOVARTIS' ADHERENCE AND EXJADE REQUESTS ARE OVERBROAD AND UNDULY BURDENSOME

Through its requests, Novartis has asked the Litigating States to search for an enormous amount of information. Novartis has asked for the "views" of every state agency on adherence programs and the activities of specialty pharmacies relating to any drug, irrespective of the disease state it is designed to treat. (Ex. CC, Req. No. 36.) These requests are not limited to any adherence programs that may exist for Medicaid recipients and instead are directed at any "policies, activities, programs, plans, or initiatives" developed by any department of each of the Litigating States. (*Id.*) Novartis has also issued requests seeking analyses by any state agency of *any* adherence program, including those operated by the private sector. (Ex. CC., Req. No. 38.) In addition, Novartis has asked for all documents about the "involvement" of specialty pharmacies in *any* of the Litigating States' health care programs. (Ex. CC. Req. No. 39.) With

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[5] Novartis did not argue in its moving brief that its adherence requests are relevant to the Litigating States' unjust enrichment claims, presumably because it is Novartis' conduct that is at issue with respect to those claims. *See Phillips Int'l Inv. LLC v. Pektor*, 117 A.D.3d 1, 4 (1st Dep't. 2014) (discussing the elements of unjust enrichment in New York). In any event, Novartis should be precluded from raising any new arguments based on the unjust enrichment claims or otherwise in its reply brief.

respect to Exjade, Novartis has asked for all documents concerning the "administration" of Exjade at any state agency or hospital, among other things.

In an effort to compromise, the Litigating States agreed to search documents from their SSAs that run their Medicaid programs about Exjade. In doing so, the Litigating States sought to narrow Novartis' requests to the drug at issue and the agency responsible for running the Medicaid programs that are at issue. Novartis rejected this offer, filed this motion, and sought the same documents through freedom of information requests.

Courts have resisted attempts by private litigants to collect irrelevant or marginally relevant documents from numerous government agencies. In one contract dispute, for instance, a court denied a motion to compel production of government contracts that contained a certain type of clause from different agencies. *U.S. v. Kellogg Brown & Root Services, Inc.*, 284 F.R.D. 22, 37-38 (D.D.C. 2012). In doing so, the court relied on Fed. R. Civ. P. 26(b)(2)(C) because the "burden and expense could be massive, and these productions are unlikely to yield much directly relevant information." *Id.*

The same is true in this case. Novartis would have the Litigating States search for every document expressing "views" about adherence programs, regardless of whether they relate to Exjade or AIDS medications and regardless of who ran the program or how they were compensated. Likewise, Novartis would have the Litigating States search for any document about the "involvement" of specialty pharmacies in any "government sponsored activit[y]." Not only are such documents irrelevant, as discussed above, but collecting, reviewing, and producing any such documents, if located, would be an enormous burden to the Litigating States.

III. THE LITIGATING STATES HAVE NO OBLIGATION TO OBTAIN AND PRODUCE DOCUMENTS FROM ANY STATE AGENCY OTHER THAN THEIR RESPECTIVE SINGLE STATE AGENCIES

A. The Agencies of the Litigating States Should Not be Aggregated for Purposes of Discovery

The Litigating States have consistently taken the position with Novartis that they are under no duty, and have no obligation to seek, obtain or produce any documents from any state agency or government entity other than their respective SSAs, which operate their respective Medicaid programs. For purposes of this issue, it makes no difference whether each state itself is the real party in interest or whether it is each state's SSA. As set out in the Litigating States' complaints, it is each state's *Medicaid program* that has suffered damages as the result of Novartis' illegal conduct. Nevertheless, as set out above, Novartis seeks documents from the states that are in no way limited to the Litigating States' Medicaid programs, are not relevant to the issues in this action, and that assume (without any justification or authority) that each and every state agency is somehow open and accessible to discovery at the request of each state's Attorney General. Novartis is mistaken.

The federal courts, particularly those in New York (and the state courts in California), have recently looked at this issue, deciding cases that do not support the position taken herein by Novartis. In particular, in the case of *New York ex rel. Boardman v. National R.R. Passenger Corp*., 233 F.R.D. 259 (N.D.N.Y. 2006) the State of New York, through the Commissioner of Transportation, entered into a contract with Amtrak for the enhancement of a high speed passenger rail program along the Empire Corridor. The State initiated litigation several years later alleging breach of contract and specific performance. The matter was brought before the Court on a discovery dispute when defendant requested that the State produce documents from

the Office of the State Comptroller (OSC). The State objected, claiming it was obligated only to produce documents from the Department of Transportation (DOT). As Novartis is attempting to do in the instant case, Amtrak took the position that as the lawsuit was brought in the name of the People of the State of New York, all state agencies were "parties" to the action, and/or their documents were under the custody and control of the DOT. *Id*. at 263.

The Court did not agree with Amtrak. After analyzing the differences in the creation of the Comptroller's Office and the DOT, the Court stated that, "There is a presumption that separate governmental agencies under state law will not be aggregated together without a showing of much more." *Id*. at 264; s*ee also*, *Lyes v. City of Rivera Beach, Fla*., 166 F.3d 1332, 1345 (11th Cir. 1999) (refusing to aggregate two state entities for purposes of a Title VII action in the absence of a finding that the entities are "so closely interrelated with respect to control of the fundamental aspects of the employment relationship that they should be counted together under Title VII."). The *Boardman* Court further stated, "For reasons of federalism and comity, we give great deference to the State and its Legislature to define how governmental entities are to be separate and distinct and how they may relate to one another as a whole; this is uniquely an exercise in state sovereignty." *Boardman* at 264.

California courts are in accord with *Boardman*. In *People ex rel. Lockyer v. Superior Court*, 122 Cal. App. 4th 1060 (Cal. Ct. App. 2004), the State appellate court expressly held that when (as here) the People of the State of California are parties to either a criminal or civil action, not all agencies and departments within the State are automatically deemed to be in possession, custody, or control of other state entities' documents and things within the meaning of the discovery rules. The *Lockyer* court observed that in California each agency is required to

maintain its own records, individual department heads may investigate and prosecute actions on their own, and agencies' interests are often in conflict with one another. As such, "[e]ach agency or department of the state is established as a separate entity, under various state laws and constitutional provisions." *Id*. at 1078. The court concluded that "[b]ecause of their separate organization, duties, and powers…[Cal. Code of Civil Procedure] section 2031 (production of documents) did not envision the People as being in possession, custody or control of documents created or possessed by nonparty state agencies." *Id*. at 1079.

Novartis cites to the case of *Compagnie Francaise d'Assurance Pour le Commerce Exteriur v. Phillips Petroleum Co*., 105 F.R.D. 16, 35 (S.D.N.Y. 1984) as its sole authority to support its position that, "[w]hen an agency of the government institutes suit, any obligation to disclose relevant information extends to the government qua government requiring disclosure of all documents in its possession, custody or control, not just those materials in the immediate possession of the particular agency-plaintiff." (Mov. Br. at 14.) However, the *Boardman* Court specifically rejected this position, stating: "*Phillips Petroleum's* pronouncement, in our view, is much too broad and sweeping for us to fully adopt in this case…. If we were to endorse *Phillips Petroleum's* proposition of the law, it would lead invariably to illogical consequences. Following Phillips Petroleum's and Amtrak's argument to its logical conclusion, any lawsuit brought by the State of New York would subject all twenty-two executive agencies, the legislature, the judiciary, quasi-state agencies, and possibly public authorities to disclosure scrutiny, notwithstanding their relative remoteness to the issue of the case. Not only would such a discovery mandate be unduly burdensome and cumbersome but totally untenable and outside the spirit of the Federal Rules." *Boardman*, at 266.

Novartis has failed to make any showing that the Litigating States' agencies should be aggregated for purposes of discovery in this case. To the contrary, documents at the non-SSA entities from which Novartis has sought documents are not necessarily under the control of the Attorneys General who brought this action or the SSAs who were injured by Novartis' conduct. Indeed, in several instances, the non-SSA entities from whom Novartis has sought discovery are not even part of the executive branch of state government. Selected examples appear below:

California: Novartis has sought documents from the "University of California healthcare/hospital system." (Ex. K, Req. No. 36.) However, California Government Code, section 12511 provides that, "The Attorney General has charge, as attorney, of all legal matters in which the State is interested, except the business of the Regents of the University of California and of such other boards or officers as are by law authorized to employ attorneys." As a result, the Attorney General does not have control of the documents of the University of California hospitals.

Illinois: Novartis has sought documents from the "University of Illinois healthcare/hospital system," which is an entity outside of the State's executive branch and outside of this litigation. (Ex. M, Req. No. 36.) Pursuant to the Illinois Compiled Statutes, "[t]he general management, control and operation of the University of Illinois Hospital shall be in the University." 210 ILCS 330/2. The "University" is statutorily defined as "[t]he Board of Trustees of the University of Illinois." 110 ILCS 330/1. As explained by the Supreme Court of Illinois: "In the sense that [the University of Illinois] is a department or branch of the State government, the University of Illinois is not an agency or instrumentality of the State. It is a separate corporate entity, which functions as a public corporation. It is not the duty of the Attorney

General to represent either the corporation or the trustees . . . ." *Board of Trustees of University of Illinois v. Industrial Commission*, 44 Ill. 2d 207, 212 (1969).

Indiana: Novartis has sought documents from the "University of Indiana healthcare/hospital system" and the Indiana Professional Licensing Agency. (Ex. N, Req. No. 36.) However, Indiana University Health, Inc. is a private corporation formed under the provisions of the Indiana Nonprofit Corporation Act of 1991, Ind. Code §§ 23-17-1-1 *et seq*. (*See* Exhibit A to the Miller Decl. at 62-64.)[6] One of its purposes is to maintain hospitals and clinics to serve as primary teaching resources for the benefit of Indiana University School of Medicine. (*Id*. at 42-43.) "[T]he relationship of Indiana University to the Corporation is not one of ownership … nor is the State of Indiana or any unit or instrumentality thereof legally or morally responsible for the financial obligations of th[e] Corporation." (*Id*. at 50.) The Indiana University healthcare/hospital system is clearly independently run, organized, and managed. As a result, if the office of the Indiana Attorney General needed documents from the Indiana University healthcare/hospital system it would be required to serve them with subpoenas.

The Indiana Professional Licensing Agency (the "ILPA") is an entity created to perform administrative functions, duties, and responsibilities for some 42 boards or other entities covering professions as wide ranging as accountants, auctioneers, cosmetologists and barbers, massage therapists, plumbers, and pharmacists. Ind. Code §25-.05-5-1 *et seq*. and 25-.05-7-1 *et seq*. Each of the boards or other entities is an independent agency created under a statute, *e.g.*, the Indiana Board of Pharmacy was created under Ind. Code §25-26-13-3. As a result, if the

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[6] "Miller Decl." refers to September 29, 2014 Declaration of Christopher Y. Miller, which was submitted to the Court in connection with this Memorandum.

office of the Indiana Attorney General needed documents from the ILPA, or any of the agencies the ILPA serves, it would be required to serve them with subpoenas.

Maryland: Novartis has specifically sought documents from the University of Maryland Medical System facilities, which are administered by the University of Maryland Medical System Corporation, a private, nonprofit corporation (Ex. O, Req. No. 36.) *See* Md. Education Code Ann. § 13-301, *et seq.*

Michigan: Novartis has sought documents from the "University of Michigan healthcare/hospital system." (Ex. P, Req. No. 36.) However, the University of Michigan, Michigan State University and Wayne State University are constitutionally created entities in the State of Michigan with their own legal counsel and are not represented by the Attorney General of the State of Michigan. *See*, MI. Const. 1963 Art. 8, sec. 5.

New Jersey: The New Jersey State hospitals from whom Novartis seeks documents are not within the control of the Attorney General or New Jersey's SSA, the Department of Human Services, Division of Medical Assistance and Health Services (DMAHS). (Ex. Q, Req. No. 36.) Rather, as explained in more detail below, each such body arises from enabling legislation that grants each such body independent powers, responsibilities, policy-making functions, and liability. In no case does a state hospital's enabling legislation link such institution, in any material fashion, to the state's SSA and, thus, in no way does the state SSA become the custodian of records for such institutions.

One example of enabling legislation for a state operated hospital/medical training facility is the law that created the University of Medicine and Dentistry of New Jersey ("UMDNJ"), *N.J.S.A.* 18A:64G-1 (Medical and Dental Education Act of 1970). This legislation was repealed

effective July 1, 2013 when various state-created entities, including UMDNJ, were restructured to be within the control of Rutgers, The State University (Rutgers) pursuant to *N.J.S.A.* 18A:64M-1, et seq. (New Jersey Medical and Health Sciences Education Restructuring Act, hereinafter "Restructuring Act"). The current enabling legislation for UMDNJ states that UMDNJ "is a body corporate and politic that operates programs of medical, dental, nursing, public health and health-related professions and health sciences education in the State of New Jersey...." *N.J.S.A.* 18A:64M-2d. A complete recitation of the control for each portion of UMDNJ and its related branches is set forth in the Restructuring Act. Specifically, the Restructuring Act states that the "facilities of the schools, institutes, and centers of the University of Medicine and Dentistry of New Jersey ... [ ] ... are hereby transferred to Rutgers, The State University...." *N.J.S.A.* 18A:65-94(3)(a). This transfer of control to Rutgers, The State University, specifically includes "all files, books, papers, records, equipment, and other property of the schools, institutes, and centers of the University of Medicine and Dentistry of New Jersey...." *N.J.S.A.* 18A:65-95(4)(c). Similarly, all "orders, rules, or regulations heretofore made or promulgated by the schools, institutes, and centers of the University of Medicine and Dentistry of New Jersey or by the University of Medicine and Dentistry of New Jersey on their behalf, shall be continued with full force and effect as the orders, rules, and regulations of Rutgers, The State University...." *N.J.S.A.* 18A:65-95(4)(d). Likewise, all lawsuits, proceedings and legal actions of any kind involving UMDNJ are to be "prosecuted or defended in the same manner and to the same effect by Rutgers, The State University...." *N.J.S.A.* 18A:65-96(5). As demonstrated through this illustrative enabling legislation, UMDNJ is under the control of Rutgers.

Rutgers, formerly a private university, has been recognized by the New Jersey courts as a "hybrid" public-private university. *Trustees of Rutgers v. Richman*, 41 N.J. Super. 259, 289-90 (Ch. Div. 1956). As such, Rutgers retains the trappings of a private college, such as an internally controlled in-house counsel department, control over its own litigation (for which it hires private counsel), and a dual board, which includes trustees not selected by the Governor or legislature. Because Rutgers has its own in-house counsel and controls its own litigation, and UMDNJ is now within the ambit of Rutgers, just as legal issues relating to Rutgers are handled by Rutgers, such issues relating to UMDNJ are handled by Rutgers. Thus, for purposes of discovery in this litigation, UMDNJ is wholly outside the control of the state's SSA.

Oklahoma: The Oklahoma Attorney General's Office has no legal or practical ability to produce documents beyond the control of Oklahoma's SSA in this matter. A "State Hospital," as defined by Novartis, is "a hospital funded and operated by the government [of Oklahoma]." (Ex. S at ¶ 25.) Novartis is seeking information from the "University of Oklahoma healthcare/hospital system" and "the Oklahoma State University healthcare/hospital system." (Ex. S, Req. No. 36.) While Oklahoma has two hospital authorities associated with the universities and which receive funding from the State of Oklahoma neither of these authorities operates the hospitals with which it is associated.

The University Hospitals Authority is associated with the University of Oklahoma Medical Center and the OU Medical Center d/b/a Children's Hospital, but it does not operate the hospitals. In 1998, the UHA entered into an operating agreement with HCA Health Services of Oklahoma, Inc, a private, for-profit company, to manage the OU Medical Center and Children's Hospital. OU Medical Center is merely a trade name under which HCA Health Services of

Oklahoma operates. As such, neither OU Medical Center nor Children's Hospital is a "state hospital" as defined by Novartis and beyond the control of both the Oklahoma Attorney General's Office and Oklahoma's SSA.

Similarly, in March of 2014, the OSU Medical Authority entered into an operating agreement with Mercy Health System, a private, for-profit company, to manage the Oklahoma State Medical Center. Prior to 2013, the OSU Medical center was operated by a City of Tulsa trust. In both cases, the OSU Medical Center was not and is not a "state hospital" as defined by Novartis and is beyond the control of both the Oklahoma Attorney General's Office and Oklahoma's SSA.

Washington: Novartis has sought documents from the "University of Washington healthcare/hospital system." (Ex. T, Req. No. 36.) The hospitals associated with the University of Washington system are not controlled by the State of Washington executive branch of government. Rather, governance of the University of Washington is vested in a board of regents. RCW 28B.20.440; RCW 28B.20.100(1).

B. The Litigating States' Single State Agencies Do Not Have "Control" of Medicaid Providers' Documents for Purposes of Discovery

A party may only be compelled to produce documents that are in its "possession, custody or control." Fed. R. Civ. P. 34(a)(1). Federal courts have consistently held that documents are deemed to be within the "possession, custody or control" for purposes of Rule 34 if the requested party has *actual* possession, custody or control, or has the legal right to obtain the documents on demand. *In re Bankers Trust Co*., 61 F.3d 465 (6th Cir. 1995); *Clark v. Vega Wholesale Inc*., 181 F.R.D. 470 (D. Nev. 1998). While this rule applies to documents within a party's control that may be in the possession of third parties, a party seeking the production of documents bears

the burden of establishing the opposing party's control over those documents. *In re Flag Telecom Holdings, Ltd. Sec. Litig*., 236 F.R.D. 177 (S.D.N.Y. 2006). Novartis has not met this burden.

According to Novartis, the Litigating States' SSAs have "nearly plenary authority" to administer state Medicaid programs, and therefore they must have control over the documents of all Medicaid providers, including state hospitals that provide services to Medicaid recipients. (Mov. Br. at 15.) However, none of the regulations cited by Novartis come close to establishing that the SSAs have control over the types of documents sought by Novartis. Moreover, the SSAs do not have the authority to get documents from Medicaid providers to respond to requests from private litigants. In New York, for instance, Medicaid providers agree to submit to "audits … relating to services furnished and payments received" by the SSA, which is the Department of Health. 18 N.Y.C.R.R. § 504.3(g). This hardly gives New York's SSA the right to documents on demand. Rather, it gives New York's SSA the right to get documents in connection with audits. Nothing in these regulations suggests that New York's SSA can demand documents from a Medicaid provider to fulfill a discovery demand from a private litigant. The court in *SEC v. Tourre* reached a similar conclusion. No. 10 Civ. 3229, 2011 WL 350286, at *3 (S.D.N.Y. Jan. 31, 2011). After analyzing a memorandum of understanding concerning the exchange of documents, it denied a motion to compel because the memorandum did not provide for the exchange of documents when sought by private litigants in discovery. *Id.*

Finally, Novartis' argument proves too much. If the SSAs in the Litigating States had control over the documents of all Medicaid providers, which they do not, it would mean that the SSAs had control over the documents of every doctor and pharmacy in their respective states

who provided services to Medicaid recipients. Thus, according to Novartis, it can take *party* discovery of private doctors, private hospitals, or private pharmacies through the Litigating States as long as they are enrolled Medicaid providers. This absurd result stems from Novartis' improper conflation of the right to regulate Medicaid providers and the concept of control for purposes of discovery. Accordingly, Novartis' motion to take discovery from agencies other than the Litigating States' SSAs should be denied.

CONCLUSION

For the foregoing reasons, the Court should deny Novartis' motion to compel.

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Respectfully submitted,

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